K081983

Philips Medical Systems

AUG 22 2008

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR §807.92.

The submitter of this premarket notification is:

Claire Arakaki
Regulatory Affairs Specialist
Patient Monitoring
Philips Medical Systems
3000 Minuteman Road, MS0480
Andover, MA 01810-1099

Tel: 978 659 4348
Fax: 978 685 5624
Email: claire.arakaki@philips.com

This summary was prepared on 8 July 2008.

The name of this device is the M3290A IntelliVue Information Center Software, Release L.0

Classification names are as follows:

Classification	ProCode	Description
none	74 MHX	Physiological Monitor, Patient Monitor
870.1025, II	74 DSI	Arrhythmia Detector and Alarm
870.1025, II	74 MLD	Monitor, ST Alarm
870.2800, II	74 DSH	Recorder, Magnetic Tape, Medical
870.2300, II	74 MSX	System, Network and Communication, Physiological Monitors

2. The new device is substantially equivalent to the previously cleared M3290A IntelliVue Information Center Software, Release J.0 marketed pursuant to K062271, K050742, K041741, K040955, K040357, K031403, K023698, K021422, K011093, K001057, K000854, K993907, K993171, and K964832.

3. The modification made to the device include the addition of the following features:

- Support for the Wireless TAAP feature
- Addition of the Manual Data Laboratory (Lab) Entry application
- Support of the ST baseline synchronization with the IntelliVue MPxx Patient Monitors
- Support for the printing of the predefined reports generated from the wireless IntelliVue MPxx Patient Monitors
- New data communication protocol used between the IntelliVue Patient Monitors and the IIC (SCADA protocol)

3000 Minuteman Road
Andover, Massachusetts 01810
Tel: (978) 687 1501, Fax: (978) 794 7646
www.medical.philips.com

p1/2

- Support for the Philips patient monitors operating in the Customer Supplied Clinical Network (wireless network)
- Addition of HL7 parameters for VistA compliance
- Integration of the ST/AR J.0 algorithm (K080461)

5. The new device has the same Indications for Use and Intended Use as the legally marketed predicate devices.

6. The new device has the same technological characteristics as the legally marketed predicate devices.

7. Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the new device with respect to the predicate. Testing involved system level tests, performance tests, and safety testing from hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate device and test results showed substantial equivalence. The results demonstrate that M3290A IntelliVue Information Center Software, Release L.0 meets all defined reliability requirements and performance claims.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 22 2008

Philips Medical Systems
c/o Ms. Claire Arakaki
Regulatory Affairs Specialist
3000 Minuteman Road, MS0480
Andover, MA 01810-1099

Re: K081983
Trade/Device Name: M3290A IntelliVue Information Center Software, Release L.0
Regulation Number: 21 CFR 870.1025
Regulation Names: Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Regulatory Class: Class II
Product Code: MHX, DSI, MLD, DSH, MSX
Dated: August 6, 2008
Received: August 8, 2008

Dear Ms. Arakaki:

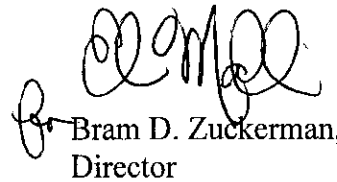
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081983

Device Name: M3290A IntelliVue Information Center Software Release L.00 (for M3140, M3145, M3150, M3151, M3154, M3155, M3169, M3170, and M3177)

Indications for Use:

Indicated for central monitoring of multiple adult, pediatric, and neonatal patients; and where the clinician decides to monitor cardiac arrhythmia of adult, pediatric, and neonatal patients and/or ST segment of adult patients to gain information for treatment, to monitor adequacy of treatment, or to exclude causes of symptoms.

Prescription Use Yes (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use No (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K081983